

### **REMARKS**

Claims 1-6 are pending.

New claim 6 is essentially identical to claim 5 except claim 6 does not recite the term "unlabeled." No new matter has been added by way of the above-amendment.

### **Interview**

Applicants note with appreciation that Examiner Habte conducted a personal Interview with Applicants' representative, Garth M. Dahlen, Ph.D., Esq. (#43,575) on August 28, 2006. Examiner Habte was very helpful in clarifying the outstanding issues. Applicants respectfully submit that the Examiner's comments on the Interview Summary Form dated August 30, 2006 adequately describes the substance of the Interview.

### **Issues under 35 U.S.C. 102(b)**

The Examiner has maintained the rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Kaspersen et al. (Journal of Label. Comp. and Radiopharm., Vol. 27, No. 9, 1055, 1989). Applicants respectfully traverse the rejection.

Applicants' comments regarding the patentable distinctions between claims 1-5 and the teachings of Kaspersen et al. as appearing in the July 20, 2006 Amendment are herein incorporated by reference.

Applicants now comment on the patentable distinctions between claims 5 and 6 and the teachings of Kaspersen et al.

Throughout prosecution, the Examiner has relied upon the experimental workup of compound 1c (in the paragraph bridging pages 1065-1066 of Kaspersen et al.) for anticipating the instantly claimed invention based upon a theory of inherency, i.e., that the <sup>13</sup>C labeled mirtazapine compound 1c is inherently formed into crystals having (i) a water content of not more than 0.5% by weight and (ii) a hygroscopic degree of not more than 0.6% by weight when

the crystals are stored in the air having a relative humidity of 75% at 25°C under atmospheric pressure for 500 hours, as presently claimed. However, instant claims 5 and 6 each recite a feature of the mirtazapine product which is distinct from an explicitly recited property of the compound 1c - the melting point. Instant claims 5 and 6 recite that the mirtazapine crystals have a melting point of 114-116°C. This is in distinction to the teachings of Kaspersen et al. which recite that the melting point of the mirtazapine product 1c is 123.8-125.8°C.

As the MPEP directs, all the claim limitations must be taught or suggested by the prior art to establish a *prima facie* case of anticipation. See MPEP §2131. In view of the fact that Kaspersen et al. do not teach (explicitly or implicitly) or suggest mirtazapine crystals having a melting point of 114-116°C, as presently claimed, a *prima facie* case of anticipation cannot be said to exist. For the reasons set forth in the July 20, 2006 Amendment coupled with the reasons given hereinabove, withdrawal of the rejection over claim 5 is respectfully requested.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Garth M. Dahlen, Ph.D., Esq. (Reg. No. 43,575) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for

Application No. 10/743,740  
Supplemental Amendment dated September 11, 2006  
Reply to Office Action of February 23, 2006

Docket No.: 1422-0619P

any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: September 11, 2006

Respectfully submitted,

By



Gerald M. Murphy, Jr.

Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant